

## REMARKS/ARGUMENTS

### Priority

The office alleged that the applicant would not have complied with the conditions for receiving the benefit of an earlier filing date as the disclosure of the prior filed applications would fail to provide adequate support. Specifically, the office noted that "The instant claimed "second energy source", "second energy detect", " ... without passing across a wall of a tip", and "without the portion of the first energy passing across the wall" do not appear to have support in the said priority documents".

The applicant respectfully disagrees and points to PCT/US02/17009, paragraph spanning page 17 and 18, which reads: "...Particularly preferred modifications of contemplated automatic pipettes will include at least one of a **volume sensor** and a **tip height sensor**. For example, one particularly preferred volume sensor may employ a **laser beam within the pipette tip**, wherein the laser beam is employed to **determine the height** (and with this the volume) **of the aspirated liquid within the tip**. Another especially preferred aspect includes an **ultrasound (or second laser) beam** that is employed to **determine the distance between the fluid dispensing end of the pipette tip and a surface** to which the fluid is to be dispensed.

Similarly, the paragraph spanning pages 9 and 10 reads: "...an **energy source** and an **energy detector** operationally coupled to fluid receiving element; wherein the **energy source provides an energy to a volume of a fluid disposed within the fluid receiving element**, wherein the **fluid reflects at least part of the energy** provided by the energy source, and wherein the **energy detector detects the reflected energy**; and a processor operationally coupled to the energy detector that calculates the volume of the fluid in the fluid receiving element using the detected reflected energy..."

It is well established that if a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met. See, e.g., *Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1116; *Martin v. Johnson*, 454 F.2d 746, 751,

*172 USPQ 391, 395 (CCPA 1972)* (stating "the description need not be in *ipsis verbis* [i.e., "in the same words"] to be sufficient").

In the instant case, it is abundantly clear to a skilled artisan that where a laser beam is employed **within** the tip, and where the **deflected energy** is measured, such configuration are drawn to those in which the longitudinal tip axis and the axis of the light beam coincide. There is absolutely nothing in the prior applications that would preclude support for the presently claimed configuration. On the contrary, the claimed configuration is well supported by the prior applications. Consequently, the effective filing date should be the earliest priority date.

### **35 USC § 103(a)**

#### *The Office Misconstrued the Claims*

It examiner stated on page 6 of the office action that "... claim 1 is construed to comprise the following structural elements: a robotic arm, a pipette tip receiving element, a manipulator, a sensor, a first energy source, a first energy detector, a second energy source, a second energy detector, and a processor. The above recitation in *italic* of the instant claim (claim 1) [referring to remaining numerous remaining elements] are construed as intended uses and/or functions of the claimed device..."

The applicant respectfully disagrees, especially in view of the amendments made herein. More specifically, the claim language as amended includes various ***structures that are defined by a functional limitation***. A functional limitation is an attempt to define something by what it does, rather than by what it is (*e.g.*, as evidenced by its specific structure or specific ingredients). The office is reminded that there is nothing wrong with defining some part of an invention in functional terms. ***Functional language does not, in and of itself, render a claim improper***. In re Swinehart, 439 F.2d 210, 169 USPQ 226 (CCPA 1971). A functional limitation is often used in association with an element, ingredient, or step of a process to define a particular capability or purpose that is served by the recited element, ingredient or step (*e.g.*, Innova/Pure Water Inc. v. Safari Water Filtration Sys. Inc., 381 F.3d 1111, 1117-20, 72 USPQ2d 1001, 1006-08 (Fed. Cir.

2004)). To even more clearly point out such functional language, the applicant further amended the claims. Consequently, the examiner's claim construction is improper and should be reversed. Therefore, amended claim 1 and claims 2-6 and 8-10 comprise numerous elements that are ignored by the office.

*The Cited reference Fails to Teach All Claimed Elements*

It should be pointed out that to establish prima facie obviousness of a claimed invention, *all the claim limitations must be taught or suggested by the prior art*. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

**(1) Claims 1-3, 5-6, and 8-10** were rejected under 35 USC § 103 as being obvious over Kureshy (U.S. Pat. No. 5,141,871) in view of Sakka (U.S. Pat. No. 5,271,902). The applicant respectfully disagrees, especially in view of the amendments herein.

(a) Amended claim 1 expressly requires "...a robotic arm comprising (1) a pipette tip receiving element and (2) a manipulator, wherein the robotic arm is configured to allow translation of the pipette tip receiving element along at least two of an x-coordinate, a y-coordinate, and a z-coordinate, wherein the manipulator is configured to allow pushing of a biochip from one location in the analytic device to another location, and wherein the manipulator is further configured to allow movement of the manipulator in a linear and in a rotational motion..." Despite the office's apparent assertion to the contrary, a carousel is not a manipulator, let alone a manipulator that is configured to allow pushing of a biochip from one location in the analytic device to another location. Clearly, these claimed elements are neither taught nor suggested by any one of Kureshy and Sakka, alone or in combination.

(b) Amended claim 1 further expressly requires that "...the pipette tip receiving element further comprises a sensor, wherein the sensor is configured to allow detection of presence of a disposable polymer pipette tip..." As in the prior office action, the examiner

asserted Kureshy would teach a sensor (office action page 6, lines 10-14), referring to column 10, lines 3-9. However, this passage refers to light beam 114 that is interrupted by the descending pipette tip in the '871 patent, which ties in with the preceding passage on column 9, line 44 et seq. discussing the option of a lost pipette tip. Therefore, the examiner deems detection system 108 as the sensor. However, detection system 108 is attached to inside of the housing cover and therefore cannot be part of the pipette tip receiving element as expressly required in the amended claim. Again, the presently claimed elements are not taught by any one of Kureshy and Sakka, alone or in combination.

(c) Amended claim 1 still further expressly requires "...a first energy source and a first energy detector operably coupled to the pipette tip receiving element, wherein the first energy source is configured to allow providing of a first energy to a volume of a liquid that is aspirated into the pipette tip without passing across a wall of the tip, and wherein the first energy detector is configured to allow receiving at least a portion of the first energy from the volume without the portion of the first energy passing across the wall of the tip..." and "...a second energy source and a second energy detector structurally coupled to the pipette tip receiving element wherein the second energy source is configured to allow providing of a second energy to a surface of a biochip when the pipette tip approaches the surface of the biochip and wherein the second energy detector is configured to allow receiving at least part of the second energy from the surface..."

The office asserted that Kureshy would teach energy sources stating "...detection system comprise an energy sources (i.e. a source of light; e.g. element 110 of Figure 2; col.5, 11 13+; claim 6) and a detector (e.g. element 112 of Figure 2; col.5, 11 13+; claim 6), which read on the first/second energy source and energy detector of c1m 1." Unfortunately, such statement only supports a single energy source and not two energy sources and detectors as presently claimed. Moreover, the office argued that the energy detector would be present in the '871 patent by pointing to col. 5. However, this passage discusses the optical detection system 108 which has previously been identified by the examiner as the sensor (see above). Thus, either the sensor or the energy detector is missing in the examiner's analysis, let alone the specified functional

aspects as presently claimed. Thus, and once more, critical elements of the amended claims are not taught by any one of Kureshy and Sakka, alone or in combination.

(d) Amended claim 1 also expressly requires "...a processor electronically coupled to the first and second energy detectors, wherein the processor is configured to allow calculation of an accurate aspiration volume of a predetermined volume using a signal from the first detector..." The office generically refers to a "...microprocess for processing signals from the detector...", allegedly reading on the electronic processor of claim 1. This analysis is lacking. First, the signal from the first detector in the '871 patent is an interrupt signal of the pipette tip sensor as established by the examiner. Thus, either the sensor or the first detector is missing. Second, assuming for a moment that the 'first detector' would be the first detector of the claims, the claims still require that energy is provided to the volume of liquid in the tip without passing through the wall of the tip (*i.e.*, light is sent through the inner volume of the tip). The opposite is the case in the '871 patent, which relies on the light beam 114 to be interrupted by the tip. Third, the amended claim also requires that the processor is configured to allow control of movement of the pipette tip along a z-coordinate using a signal from the second detector. Neither the '871 patent nor Sakka provide such teaching. Again, critical elements of the amended claims are not taught by any one of Kureshy and Sakka, alone or in combination.

Therefore, and at least for these reasons, amended claim 1-3, 5-6, and 8-10 should not be deemed obvious over Kureshy in view of Sakka.

With further respect to **claim 2**, the examiner asserts that Kureshy would teach that the first energy source comprises a laser based on Kureshy's teaching of a semiconductor diode that emits infrared radiation. It is entirely unclear to the applicant how the office's position would be supported by that passage. Infrared diodes (*e.g.*, present in TV remote controls) are not lasers (*e.g.*, present in CD/DVD players), and are not an obvious variation of lasers as, *inter alia*, they do not provide the same function in the same way with the same result. Clarification is requested or the rejection should be withdrawn.

With further respect to **claim 3**, the examiner asserts that Kureshy would teach that accurate aspiration would be calculated from a reflected light signal that is detected by the first

energy detector. The examiner refers in support of his position to element 28 of Figure 2 [which is the drive motor of the carousel] and Figure 7 [depicting a graph correlating time course and tip location]. It is again entirely unclear to the applicant how the office's position would be supported by the Figures. Indeed, the '871 patent clearly teaches that microprocessor 62 provides timed control for aspiration of liquids in response to a signal from the optical detection system (e.g., column 5, line 38- column 6, line 37). There is absolutely no teaching of a calculation of an appropriate volume, let alone a calculation of a volume as a function of the reflected light signal. Additionally, as claim 3 depends on claim 2, all defects pointed out above for rejection of claim 2 apply as well. Again, clarification is requested or the rejection should be withdrawn.

With further respect to **claim 5**, reference is made to the applicant's observations for the rejection of claim 1. The cited passage refers to optical detection system 108, which is either the sensor or the second energy source/detector. Clarification is requested or the rejection should be withdrawn.

With further respect to amended **claim 8**, it is noted that the claim as amended requires a data transfer interface that is configured to allow export of data from the device. Such interface is not taught by Kureshy and/or Sakka. Similarly, with further respect to amended **claim 9**, it is noted that the claim as amended requires a data transfer interface that is configured to allow providing data to a person other than the operator, wherein that person is in a remote location relative to the analytic device. Once more, such interface is not taught by Kureshy and/or Sakka.

With further respect to **claim 10**, the examiner asserted that Kureshy would teach a sample station with a multiwell plate and a multi-reagent pack. The office points to Figure 2, elements 66 and 68 as the sample station and Figure 2 element 66 as the multi-reagent pack. This is incorrect. Element 66 is a reservoir in a table 68. If one would argue that the reservoir 66 is a multiwell plate, the multi-reagent pack is clearly not element 68. Should the office insist that the table is a multi-reagent pack, written notice to that effect is respectfully requested.

*The Cited Reference Lacks Suggestion or Motivation*

It should further be pointed out that "...*particular findings* must be made *as to the reason* the skilled artisan, with no knowledge of the claimed invention, would have selected these components *for combination in the manner claimed*..." (In re Kotzab, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000)), and that "...there must be some *motivation, suggestion, or teaching of the desirability* of making the specific combination that was made by the applicant..." (In re Dance, 160 F.3d 1339, 1343, 48 USPQ2d 1635, 1637 (Fed. Cir. 1998)).

With respect to the combination of Sakka and Kureshy it is noted that in either instance the problem faced by the inventor was solved in a favorable manner (e.g., column 12, lines 4-26). Indeed, Sakka's advantages were only achieved by passage of light through the wall of the tip (see e.g., Figures 3(a) - (d)), which is contrary to the claimed subject matter. Sakka fails to provide any motivation to modify his illumination scheme. Similarly, Kureshy solved the problem of non-pipetting using a mechanism in which presence of a tip is ascertained, and once ascertained, the tip is further lowered into the solution. Aspiration is then performed on a time-basis, which is again contrary to the claimed subject matter. Thus, Kureshy fails to motivate a person of ordinary skill in the art to modify his configuration.

With respect to the office's argument that the carousel 254 would read on the "movable manipulator" it is unclear to the applicant what the examiner intends to express. A carousel as taught by Kureshy is entirely inconsistent with a manipulator that is configured to allow pushing of a biochip from one location in the analytic device to another location, and to allow movement of the manipulator in a linear and in a rotational motion. Clarification is respectfully requested.

*Problem Solved By the Claimed Invention Is Unrecognized*

It is also pointed out that in considering motivation in the obviousness analysis, the problem examined is not the specific problem solved by the invention but the *general problem that confronted the inventor before the invention was made*. See, e.g., *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1323 (Fed. Cir. 2005). In the instant case, the general problem for integrated analyzers is limited availability of space within a housing and scheduling of numerous tasks in which the task-effecting devices are in separate locations and/or

require moving of a sample. In the present claims, numerous functionalities are integrated into the same device, which advantageously allows multi-tasking while the sample remains in the same position. Thus, complex sequences can be performed in a time-effective manner, even if multiple samples (here: multiple biochips) are processed at the same time. In contrast, the '871 patent entirely fails to recognize such solution and relies on known manners (here: use of one or more carousels).

**(2) Claims 1-6, and 8-9** were rejected under 35 USC § 103 as being obvious over Kureshy in view of Sakka and further view of Laugharn (U.S. Pat. No. 6,948,843). The applicant again respectfully disagrees, especially in view of the amendments herein.

It is noted that only claim 4 is discussed on page 11. The applicant assumes that the examiner intended to apply the combination of Kureshy, Sakka, and Laugharn to reject only claim 4. Therefore, claims 1-3, 5-6, and 8-9 are not addressed here. With respect to Kureshy and Sakka, the same defects as pointed out above apply and are not reiterated here.

With respect to Laugharn's ultrasound device it is noted that Laugharn uses the device for fluid mixing of picoliter quantities, which is entirely inconsistent with a pipetting operation. While the keyword "ultrasound transducer" is present, it does not render claim 4 obvious in the absence of proper reasoning. The examiner asserts in the office action that the motivation to combine would be to provide "...a way of mixing...to ensure accurate distribution...and more uniform uptake of the sample..." Such motivation is spurious at best as the claimed device has nothing to do with mixing fluids. Indeed, the claims require that the signal from the ultrasound transducer is used to control movement of the pipette tip along a z-coordinate. The examiner's argument is a *non-sequitur* and the combination is improper. The rejection should be withdrawn.

### **Double Patenting**

**Claims 1-3 and 5-10** were rejected under the judicially created doctrine of obviousness-type double patenting over claims 6-7 of the Kureshy patent in view of Sakka and Laugharn. The



applicant disagrees, especially in view of the amendments made herein. As the cited art is the same as for the prior 103 rejections, the same deficiencies as pointed out above apply and are not reiterated here. Based on the above arguments and amendments, the double patenting rejection should be withdrawn.

### **35 USC § 112, first paragraph**

The office rejected **claims 1-6 and 8-10** as failing to comply with the written description requirement. More specifically, the office noted that the instant specification would not provide support for a.) "provides a first energy to a volume that is enclosed by the pipette tip without passing across a wall of the tip"; b.) " ... without the portion of the first energy passing across the wall of the tip"; and c.) " ...and such that the second energy detector receives at least part of the second energy from the surface".

It is entirely unclear how the office could arrive at such conclusion. Figure 1, and the specification (*e.g.*, page 6, starting line 16) unambiguously discloses items a.) and b.) cited by the examiner. Similarly, Figure 2, and the specification (*e.g.*, page 6, starting line 32 to page 7, line 8) unambiguously discloses item c.). Moreover, further reference is made to the section above addressing priority, which is not reiterated here. Consequently, the rejection should be withdrawn.

### **35 USC § 112, second paragraph**

The office rejected **claims 1-6 and 8-10** as being indefinite for reciting the term "enclosed by" the pipette tip as such term would allegedly imply complete enclosure of the volume by the tip. It should be noted, however, that the claims are directed to the invention that is described in the specification; they do not have meaning removed from the context from which they arose. *Network, LLC v. Centraal Corp.*, 242 F.3d 1347, 1352 (*Fed. Cir.* 2001); see also *Phillips v. AWH Corp.* (*Fed. Cir.* 2005) (*en banc*). Applied to the instant case, it should be

abundantly clear from the Figures and description that the volume is enclosed by the side walls of the tip and thus allows energy delivery to the volume from the inside of the tip. Nevertheless, the applicant amended claim 1 to refer to a volume that is aspirated into the tip. Consequently, the rejection should be withdrawn.

**REQUEST FOR ALLOWANCE**

Claims 1-6 and 8-20 are pending in this application, with claims 11-20 being withdrawn. The applicant requests allowance of all pending claims.

Respectfully submitted,

FISH & ASSOCIATES, PC

By 

Martin Fessenmaier, Ph.D.

Reg. No. 46,697

Tel.: (949) 253-0944